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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,652	01/15/2002	Manuel L. Penichet	407J-001700US	8739
22798 7590 02/07/2007 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/07/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/051,652	PENICHER ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/6/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Penichet et al.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/17/2006 has been entered.
2. Claims 1-30 are pending. Claims 1-22 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 23, 25, 27, and 29 are amended.
3. Claims 23-30 are under examination.
4. The information disclosure statement (IDS) filed on 7/6/2006 has been considered. A signed copy is attached hereto.
5. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior office action.

Rejections withdrawn

6. The rejection of claim 29 under 35 U.S.C. 112, first paragraph because of new matter is withdrawn in view of applicants' amendment to the claim.

Response to Arguments

7. The rejection of claims 23-25, 26 and 28-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response states that actual reduction to practice of all targeting moieties is not required. The response states that applicants have shown adequate written description and more than adequately described the genus of targeting moieties by, e.g., giving a large number of examples (both of specific targeting moieties and types of targeting moieties as well as of a wide range of specific cell surface proteins/carbohydrates and types of cell surface proteins/carbohydrates that can be targeted by the targeting moieties), for example, paragraphs 33-34 list numerous targeting moieties and targeting moiety types (e.g., antibodies, antibodies against cell surface receptors, antibodies against specific cell surface receptors, etc.), numerous examples are also presented of cell surface proteins/carbohydrates that can be targeted by the targeting moieties (e.g., receptors, growth factor receptors, specific growth factor receptors, etc.). The response states that the targeting moieties, no matter the type or specific example, share the common property of binding a protein/carbohydrate of the cell surface.

Applicants' arguments have been carefully considered but are deemed not to be persuasive. As indicated in the previous office action, the "targeting moiety" or "ligand" encompasses a variety of molecules with different structures and functions such as proteins (including antibodies), nucleic acids, small peptides, organic compounds, inorganic ions, etc. The specification only discloses one type of targeting moiety or

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ligand, i.e. antibody, and the fragments thereof such as single chain antibody.

Therefore, the written description is not commensurate in scope with the claims which read on any and all targeting moieties or ligands. The instant specification may provide an adequate written description of the genus of a targeting moiety or a ligand by structurally describing representative species by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." In this case, applicants are claiming a genus of molecules defined solely by its function, i.e. binding to a cell surface protein or carbohydrate, which is simply a wish to know the identity of any material with that function. Although the specification discloses one type of targeting moiety i.e. antibody, this does not provide a description of the broadly claimed targeting moiety because the specification provides no functional characteristics coupled to structural features. Further, the specification also fails to describe a targeting moiety that is representative to the full scope of the genus because the specification describes only antibody. Therefore it fails to describe a representative number of such species. Because of these reasons, the rejection is deemed proper.

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8. The rejection of claims 23-30 under 35 U.S.C. 102(b) as being anticipated by Penichet et al (J. Immunol. 1999, 163: 4421-4426, see IDS) is maintained, and as evidenced by Zerega et al. (J. Cell Science, 2001, 114: 1473-1482).

The response states that Penichet does not teach the composition that comprise a targeting moiety-avidin construct along with a pharmaceutical carrier but which do not comprise biotin or biotinylated molecule.

Applicants' arguments have been carefully considered but are deemed not to be persuasive. Amendment to the claims to add limitation "wherein said composition does not comprise biotin or a biotinylated molecule" cannot overcome the instant rejection. Penichet et al. teach an antibody-avidin fusion protein specific for the transferring receptor (see abstract, and Figure 1). Penichet et al. teach an antibody-avidin chemical conjugate (see page 4422, left column, 1st paragraph). Penichet et al. teach that the purified fusion protein is stable in PBS for 1 year (see page 4423, right column, lines 1-2). Because the instant specification teaches that the pharmaceutical acceptable carriers includes any of those commonly used to deliver antibody-avidin-biotinylated drug complexes, the PBS used by Penichet reads on the claimed pharmaceutical carrier. Moreover, while Penichet et al. do not teach that their fusion protein is cytotoxic, it is considered as an inherent property of the fusion protein as evidenced by the teachings of Zerega et al. Zerega et al. teach that avidin, acting as a fatty acid biosynthesis regulator, plays a role during terminal cell differentiation by impairing cell proliferation without interfering with the differentiation process (see page 1474, 2nd paragraph). Because the fusion protein of Penichet et al. retains the function of both

antibody and avidin, i.e. its specificity for transferring receptors and ability to bind to biotin, the fusion protein of Penichet et al. would be able to inhibit cell proliferation.

9. The rejection of claims 23-30 under 35 U.S.C. 102(a) as being anticipated by WO 01/07084 (see IDS) is maintained, and as evidenced by the teachings of Kemp et al. (Pathobiology, 1992, 60: 27-32, IDS).

The response states that WO 01/07084 does not teach the composition that comprise a targeting moiety-avidin construct along with a pharmaceutical carrier but which do not comprise biotin or biotinylated molecule.

Applicants' arguments have been carefully considered but are deemed not to be persuasive. Amendment to the claims to add limitation "wherein said composition does not comprise biotin or a biotinylated molecule" cannot overcome the instant rejection. WO 01/07084 teaches a fusion protein comprising a first segment and a second segment: the first segment comprising a variable region of an antibody that recognizes transferring receptor (claims 6-7) and further comprises at least one domain of a constant region of an antibody; and the second segment comprising a protein domain selected from the group consisting of avidin, an avidin mutein, a chemically modified avidin derivative, streptavidin, etc (Claim 1). WO 01/07084 teaches an Ab-Av chemical conjugates (see page 2, last line). WO 01/07084 teaches that the fusion protein was purified from culture supernatant and protein concentration was determined by BCA protein assay (see page 28, lines 20-23). While WO 01/07084 does not explicitly teach the protein is dissolved in water or buffer, determination the protein concentration would

include a step of dissolving the fusion protein in water or buffer such as PBS. Because the instant specification teaches that the pharmaceutical acceptable carriers includes any of those commonly used to deliver antibody-avidin-biotinylated drug complexes, the PBS or water used in WO 01/07084 reads on the claimed pharmaceutical carrier.

Moreover, while WO 01/07084 does not teach that the fusion protein is cytotoxic, it is considered as an inherent property of the fusion protein as evidenced by the teachings of Kemp et al. Kemp et al. teach that monoclonal anti-transferrin receptor antibody inhibits the growth of neoplastic cells (see abstract). Because the fusion protein of WO 01/07084 retains the function of both antibody and avidin, i.e. its specificity for transferring receptors and ability to bind to biotin (see page 46, lines 5-6), the fusion protein of WO 01/07084 would be able to inhibit cell proliferation of neoplastic cells.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

10. Claims 23-26, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultz et al., (Cancer Res. 2000, 60: 6663-6669), as evidenced by Stone et al. (Proceeding Am. Assoc. Cancer Res. Annual Meeting, 2002, 43: 881, IDS).

Schultz et al. teach a tetravalent single-chain antibody-streptavidin fusion protein for pretargeted lymphoma therapy, wherein the single-chain antibody is from the CD20-specific murine monoclonal antibody B9E9 (see abstract). Schultz et al. teach that the immunoreactivity of the scFv-streptavidin fusion protein and its nanomolar affinity to CD20-positive Ramos cells were comparable with the B9E9 monoclonal antibody (see

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abstract). Schultz et al. teach a pharmaceutical carrier for the fusion protein, i.e. PBS (see page 6664, right column, 4th paragraph). Schultz et al. teach antibody-streptavidin chemical conjugates (see page 6663, right column, 3rd paragraph). While Schultz et al. do not teach that the fusion protein is cytotoxic, it is considered as an inherent property of the fusion protein as evidenced by the teachings of Stone et al. Stone et al. teach that the tetravalent single chain antibody-streptavidin fusion protein induces apoptotic in human B-lymphoma cell, wherein the single chain antibody is derived from antibody B9E9 (see abstract).

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang

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Jan. 29, 2007


CHRISTOPHER H. YAEN
PRIMARY EXAMINER